

Message

From: Culleen, Lawrence E. [Lawrence.Culleen@arnoldporter.com]
Sent: 1/16/2020 11:32:04 PM
To: Dekleva, Lynn [dekleva.lynn@epa.gov]
Subject: As Promised -- Draft Consent Order Template
Attachments: PAG Consortium Jan. 2020 Edits to EPA_s Dec. 2019 Draft_(US_166798536_21).DOCX; Discussion Draft of PAG Category Definition_20200116.pdf

Lynn --

Attached are two documents that are being submitted in the context of our on-going discussions concerning the template for Consent Orders pertinent to "PAG" substances currently under review in the New Chemical Program. The two documents are: (i) the PAG Consortium's mark-up of the edition of the draft Consent Order template you shared with me during late December 2019; and, (ii) a discussion draft of the PAG Consortium's proposed PAG Category Definition.

Consent Order Template: The changes we propose to the draft template for the Consent Order are visible in the "track changes" mode and are minimal; we trust they will be readily accepted by the Agency. The draft Consent Order template also includes a few comments in the margins containing some requests for clarifications which I understand can be addressed readily. I would be willing to meet with you in person tomorrow or to confer by phone if it would be helpful to talk through the few edits and requests for clarification with you, or your designee. The Consortium Members have suggested that, as in prior exchanges, the Agency pass-back to me a revised edition of the attached draft which clearly calls-out any further changes the Agency might make so that I can circulate that version quickly to the Consortium Members who will need to discuss any further changes among the group and within their separate businesses. Of course, if all of the changes we have proposed in the attached edition are "accepted", and you can affirmatively address our few requests for clarifications, then such an exchange might not be needed.

PAG Category Definition: The attached pdf file represents a discussion draft of the PAG Category Definition which was prepared by the Consortium's "technical team". It reflects the group's effort to describe the contours of the Category based on their mutual understanding of the structural features of PAGs which have been under review at the Agency in a manner that will enable Consortium Members to anticipate when a future Section 5 (LVE/PMN) submission will be considered within "scope" (i.e., a substance which can be added to an existing PAG Consent Order previously signed by a Consortium Member/PMN submitter), or "out of scope" (i.e., a substance for which EPA might want to receive certain test data). The Consortium Members would like to schedule a discussion to include the Consortium's "technical team" members and their counterparts among the scientists within the Agency's New Chemicals Program personnel. Given the Agency's desire to conclude discussions on the Consent Order template this month, we recognize that it might be difficult to schedule a substantive and helpful discussion of the proposed Category Definition before the end of January. Thus, we recommend retaining the more simple definition that currently appears in the draft Consent Order with the understanding that the Agency is committed to engaging in collaborative discussions on the attached Category Definition at a future date -- if necessary, after the Consent Orders have been signed. We would anticipate such discussions will enable us to have a dialogue on the issue of "scope" (i.e., identifying those substances that, through future PMN submission made by Consortium Members, can be added to the company-specific Consent Orders). Those discussions also should address the appropriate vehicle for such future submissions (e.g., through initial LVEs that can be granted subject to time limitations to be followed by PMNs only after the "scope" discussion have concluded).

LVE Time Limitations/Extension: Finally, we understand the Agency will issue extensions through the end of the month of any time limitations for Members' LVEs that might expire before that date. The purpose of such extensions will be to reach closure on the final Consent Order template terms and provide sufficient time for the company-specific Consent Orders to be timely prepared by EPA, issued, received, and reviewed by the affected Consortium Members/PMN submitters.

Do call me if you have any questions; and please advise if I should schedule some time to meet with you in person Friday.

Larry

Lawrence Cullen

Partner

Arnold & Porter

601 Massachusetts Ave., NW

Washington | District of Columbia 20001-3743

T: +1 202.942.5477

Lawrence.Cullen@arnoldporter.com | www.arnoldporter.com

This communication may contain information that is legally privileged, confidential or exempt from disclosure. If you are not the intended recipient, please note that any dissemination, distribution, or copying of this communication is strictly prohibited. Anyone who receives this message in error should notify the sender immediately by telephone or by return e-mail and delete it from his or her computer.

For more information about Arnold & Porter, click here:
<http://www.arnoldporter.com>